Protocol: Tug Endotracheal Tube to assess tube location; a randomized clinical trial

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Introduction

Correct endotracheal tube (ETT) placement is important. Ideal ETT position is achieved when the distal tip is in mid-trachea with the head in neutral alignment. Unrecognized tube misplacement is an uncommon but significant cause of hypoxemia and death during general anesthesia and emergency intubation of critically ill patients. It is commoner in out-of-hospital intubations, where it is reported to occur in 1 to 15% of cases, often with disastrous results. [1, 2]

Three types of malpositioning can occur: one outside the trachea (esophageal), and two within the trachea: too shallow (hypopharyngeal), or too deep (endobronchial). Esophageal intubation results in rapid hypoxemia, hypercarbia, and inflation of the stomach as the patient receives no ventilation at all. [3] Too-shallow placement of the ETT can result in inadvertent extubation, especially with manipulation of head and neck. [4] Endobronchial intubation occurs when the ETT is advanced into a mainstem bronchus, which results in hypoxia and the potential for barotrauma in the hyperventilated lung. [5, 6]

Confirmation of correct ETT depth is currently performed by several methods. In the operating room, simple measurement of the length of the tube at the corner of the mouth is rapid but not reliable. One study improved on this by using additional anatomical landmarks to determine ETT tube length as measured at the mouth.[7] It enabled a reduction in the incidence of too-deep placement of the ETT from 58.8% to 24%.

Cuff ballottement at the level of the suprasternal notch is a technique that has been studied with cuffed tubes in adults. Ballottement as described in these papers involves moving the fingers in a direction normal to the long axis of the ETT in order to alternately compress and release the finger pressure on the cuff, while feeling and watching the corresponding movement of the pilot balloon. Ease of palpation of ballottement was inconsistent, and in one study 15 of 82 patients had ETT tips <2.5 cm above the carina. [8-10] Studies to date of ballottement do not comment on its ability to prevent esophageal intubation. Ultrasound guided intubation has been shown to provide correct placement, but requires training and machine availability. [11-14]

We proposed to refine methods of palpating the trachea that we studied in previous experiments. We found that palpation of the anterior trachea with the fingertips during intubation enabled us to feel the tip of the endotracheal tube sliding into the trachea and improve correct depth compared to measurement at the teeth. [15] That study was undertaken to determine whether palpation of the trachea could enable correct position of the endotracheal tube with respect to depth. Esophageal intubation was studied subsequently, but the study was stopped when it became clear that we could not determine esophageal intubation by anterior tracheal palpation (unpublished).

However, during two instances of inadvertent esophageal intubation, we accidentally discovered a technique that may be able to detect inadvertent esophageal intubation as well as ensure correct endotracheal tube depth.[A] Following tracheal intubation, with the cuff inflated to 50cm water pressure in the trachea, there was a sudden marked increase in the force necessary to gently tug the endotracheal tube proximally as the inflated cuff impinges on the rigid, encircling cricoid cartilage. When the increased force is sensed, then pushing the ETT down 2cm will ensure it is correctly positioned. If the cuff is in the esophagus, it will slide out without the sudden increased force being felt.

[A] In describing this technique, we will refer to the tip of the endotracheal tube that goes in the trachea as distal or down, and the opposite end of the endotracheal tube that is attached to a ventilating device as proximal or up.

We plan a clinical pilot study of intubation of esophagus versus trachea with initial intubation of the esophagus flowed by intubation of the trachea.

Hypotheses. The force required for esophageal extubation with cuff inflated will be that required for tracheal extubation.

Primary outcome. To assess the reliability and accuracy of TETT as a method to determine tracheal versus esophageal intubation by measuring the force needed to slowly pull the ETT from the esophagus versus from the trachea.

Secondary outcomes. To find the optimal cuff-inflation pressure to distinguish trachea from esophagus and to assess the reliability and accuracy of TETT as a method to determine depth of endotracheal tube in the trachea.

Experimental design. A clinical trial with an objective measure of the difference in force of tugging between esophagus and trachea.

Patient safety. Intentional esophageal intubation has been reported in three previous airway studies with no harm coming to 275 patients. [16-18] Intentional intubation of the esophagus has been practiced routinely for gastroscopy in millions of patients. Mortality attributable to esophageal endoscopy is exceedingly low (0.005-0.01%), includes very sick patients, and occurs only with interventions such as biopsy and cautery of esophageal varices.[19] In a prospective study of resident trainees performing upper G.I. endoscopy (N = 4,490), there were no complications attributable to insertion of the gastroscope in the upper third of the esophagus.[20]

The manoeuvre takes only about 10 seconds, then the opposite orifice can be intubated, with mask oxygenation between intubations if indicated. In a just-completed study of moving and ETT upward in the trachea with the cuff inflated to 50cm H2O pressure we found no increase in sore throat as a surrogate for tracheal damage in patients who had the ETT moved with cuff inflated compared to standard care (manuscript in preparation). [21] A recent study conducted at University of Saskatchewan showed that there is great variance in cuff inflation pressures clinically (manuscript in preparation), with pressures often exceeding 120 cm H2O pressure with no apparent adverse effects for inflation during surgery.

Clinical Utility. If this technique proves reliable, it can decrease the risk of ETT misplacement. Further, if it is reliable, it is particularly useful because it takes no special equipment, can be performed in less than 10 seconds anywhere from operating room to battlefield, and may make xray confirmation of ETT depth unnecessary, avoiding radiation and expense.

Methods

Participants:

1. Patients: Following University of Saskatchewan Research Ethics Board and Saskatoon Health Region approval, informed consent will be obtained from 20 patient participants. The collection, use and disclosure of patients' private information will conform to the Health Information Protection Act (HIPA). A convenience sample of American Society of Anesthesiologists (ASA) Class I and II patients ≥18 years, undergoing elective surgical procedures in the Saskatoon acute care hospitals of the Saskatoon Health Region and requiring endotracheal intubation as a component of the anesthetic plan, will be recruited. [22] Recruitment will take place in the Pre-Admission Clinic (PAC); in the Same Day Surgery and Day Surgery admission areas; and in the Operating Room (OR) Holding Area. Excluded patients will be those who are physiologically unstable, if there is urgency to proceed with surgery, patients requiring rapid sequence induction, and those with respiratory distress. The

anesthesiologists will be encouraged to exclude patients if for any reason they feel that inclusion puts them at risk.

2. Testers: we will recruit and explain the manoeuvre to willing anesthesia staff, residents, and anesthesia assistants.

Interventions: Intubation will be by the attending anesthesiologist, who will choose the intubating anesthetic and equipment on clinical grounds. The anesthesiologists will intubate the esophagus first, and inflate the ETT cuff to their customary pressure, which we will then measure. An apparatus including a force transducer (LoadStar F-152217557 S-beam sensor run on LoadVue software; Loadstar Sensors Ltd., Fremont CA, USA) will be attached to the ETT connector and the testers will perform the gentle tugging while recording the force of pull until the ETT comes out of the esophagus. The process will be repeated with the trachea. At this point the anesthesiologist will intubate the trachea and proceed with surgical anesthesia. Only one set of intubations will be tested on any participant.

Measurements: Data will be recorded on paper data sheets for later transcription to a computer spread sheet for analysis. Usual demographics (age, gender, height, weight, type of surgery) will be recorded. Force transducer data will be digitally recorded on a computer for later analysis.

Sample size. Assuming that the anesthesiologist is able to intubate the esophagus successfully 100% of the time in this population, and the palpation technique is able to detect the esophageal intubation correctly only 50% of the time, we will need 15 participants assuming an alpha value of 0.05 and a beta value of 0.2 with Yates correction. Because a previous study showed that we can palpate the trachea successfully for the purposes of depth measurement in only 90% of cases, we will assume 10% of tugs result in "N" – "unable to determine if there is or is not a change in tug force", this would bring the sample number up to 17. Therefore, accounting for unforeseen exigencies, we will plan to recruit 20 participants.

Statistical Analysis: Demographics will be reported. Forces will be compared with paired t-tests.

Table 1. Diagnosis of esophageal intubation.

Test ↓ Truth →	T	E	totals
T			
E			
totals			

We will plot and subtract the force change from esophagus from the force change from trachea at the various pressures and construct a receiver operating curve to show the optimal cuff inflation pressure.

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